Docket No.: C1037,70042US00 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Arthur M. Krieg Serial No.: 10/613.524 Confirmation No : 4728

Filed: July 3, 2003

For: NUCLEIC ACID COMPOSITIONS FOR STIMULATING IMMUNE

RESPONSES Examiner: O. A. Ogunbiyi

Art Unit: 1645

Certificate of Electronic Filing Under 37 CFR 1.8

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4),

Dated: April 27, 2009

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR \$1.705

Mail Stop Issue Fee Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Madam:

In accordance with 37 CFR \$1.705(b), Applicant requests reconsideration of the patent term adjustment ("PTA") for U.S. Application No. 10/613.524 ("the '524 Application"). Applicant provides, below, a statement of the facts involved, specifying the correct PTA and the bases under 37 CFR §1.702 for the adjustment, the relevant dates for which adjustment is sought, and the adjustment to which the patent is entitled.

- 1. On January 27, 2009, the U.S. Patent and Trademark Office ("USPTO") mailed a Notice of Allowance and Determination of Patent Term Adjustment (Exhibit 1) for U.S. Application No. 10/613,524, which indicated that the '524 Application was entitled to a patent term adjustment of 752 days.
- 2. According to the Patent Term Adjustments page (Exhibit 2) on the Patent Application Information Retrieval (PAIR) system, the USPTO accorded the '524 Application a patent term adjustment of 941 days for delays that occurred at the USPTO and reduced the PTA by 189 days for delays that Applicant allegedly incurred.

Application No. 10/613,524 Confirmation No. 4728

- Applicant submits that the correct PTA should be at least 1,254 days, which is the net USPTO delay of 1,517 days minus the apparent net Applicant delay of 263 days.
- 4. The USPTO delay resulted from the USPTO taking two actions outside the time periods allowed under U.S. Patent Law and Rules of Practice in Patent Cases. The first, which was noted on the PTA page of PAIR, was the USPTO's failure to mail a first notification under 35 U.S.C. § 132 within the 14-month period following the filing date of the application. See 35 U.S.C. § 154(b)(1)(A)(i); See also 37 CFR §§ 1.702(a)(1) and 1.703(a)(1). Although the 14-month period following the actual filing date of the application ended on 09/03/2004, the USPTO did not mail a first notification (a Restriction Requirement) until 04/02/2007. This period of time, from 09/04/2004 through 04/02/2007, resulted in a USPTO delay of 941 days.
- 5. The second component of the USPTO delay, which was not included on the PTA page of PAIR, resulted from the USPTO's failure to issue the '524 Application within three years of its actual filing date, 07/03/2003. See 35 U.S.C. § 154(b)(1)(B). Although the issue date of the '524 Application is unknown, Applicant filed a Request for Continued Examination (RCE) on 10/30/2008, which resulted in an exclusion of time from that date forward. See 35 U.S.C. § 154(b)(1)(B)(i). The period of delay thus began on the first day following the three-year period, 07/04/2006, ended on 10/29/2008, and resulted in a USPTO delay of 849 days.
- 6. The net USPTO delay of 1,517 days is the sum of the two delay periods (941 days and 849 days) minus the number of days the two periods overlap on the calendar (273 days). See Wyeth v. Dudas, 580 F. Supp. 2d at 138, 141 (D.D.C. 2008) (holding that the "only way that periods of time can 'overlap' is if they occur on the same day"). The period of overlap occurred from 07/04/2006 through 04/02/2007.
- 7. The apparent Applicant delay resulted from two instances of Applicant filing a response more than three-months after the mailing date of an Office Action and three instances of Applicant filing supplemental replies that were ostensibly not expressly requested by the Examiner. See 37 CFR §§ 1.704(b) and 1.704(c)(§). With respect to the former delays, which were noted on the PTA page of PAIR, the USPTO mailed a Non-final Office Action on 06/27/2007, and in response, Applicant filed an Amendment on 01/02/2008. This resulted in an apparent Applicant delay of 97 days for the period from 09/28/2007 through 01/02/2008. In addition, the USPTO mailed a Final Office Action on 04/30/2008, and in response. Applicant

filed an After-final Amendment and an RCE on 10/30/2008. This resulted in an apparent Applicant delay of 92 days for the period from 07/31/2008 through 10/30/2008.

- 8. Following the submission of the RCE on 10/30/2008, Applicant filed a series of Information Disclosure Statements on 12/10/2008, 12/22/2008, and 01/12/2009. If considered to be supplemental replies, these submissions may result in Applicant delays of 41 days (period from 10/31/2008 to 12/10/2008), 53 days (period from 10/31/2008 to 12/22/2008), and 74 days (period from 10/31/2008 to 01/12/2009). See 37 CFR § 1.704(c)(8). None of these apparent delays were included on the PTA page of PAIR.
- 9. The apparent net Applicant delay of 263 days is the sum of the apparent Applicant delay periods (97, 92, 41, 53, and 74) minus the number of days the periods overlap on the calendar (94 days). The periods of overlap occurred from 10/31/2008 through 12/10/2008 and from 10/31/2008 through 12/22/008.
- 10. Applicant filed a Telephone Interview Summary on 01/20/2009, which documented three telephone interviews that were held on 01/05/2009, 01/12/2009, and 01/15/2009 between Applicant's representative and the Examiner. Applicant submits that this document should not result in Applicant delay because it was expressly requested by the Examiner. See Part III of the Examiner-Initiated Interview Summary (Exhibit 3), which was included with the Notice of Allowance mailed 01/27/2009, and which indicates that the Examiner did not relieve Applicant of the need to file a separate record of the substance of the interview.
- 11. A terminal disclaimer was not filed in this case and the '524 Application is not subject to a terminal disclaimer.

Conclusion

Based on the foregoing, Applicant respectfully submits that the correct patent term adjustment should be at least 1,254 days as opposed to the 752-day PTA listed in the Notice of Allowance. The additional days of patent term adjustment result from the USPTO's failure to issue the '524 Application within 3 years of its filing date. This delay period may be partially offset by Applicant's filing three Information Disclosure Statements following the submission of an RCE.

Date: April 27, 2009

x04.27.09

Docket No.: C1037.70042US00

Applicant submits \$200.00, which is the fee set forth in 37 CFR § 1.18(e) for filing an application for patent term adjustment. If there is any additional fee occasioned by this application and request that is not covered by the enclosed fee, please charge any deficiency to Deposit Account No. 23/2825 under Docket No. C1037.70042US00 from which the undersigned is authorized to draw.

Respectfully submitted,

Maria A. Trevisan

Registration No.: 48,207

WOLF, GREENFIELD & SACKS, P.C.

Federal Reserve Plaza 600 Atlantic Avenue

Boston, Massachusetts 02210-2206

617.646.8000





UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS Adexandria, Viginia 22313-1450 www.upipo.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 01/27/2009

Maria A. Trevisan Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210 EXAMINER

OGUNBIYI, OLUWATOSIN A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 01/27/2009

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/613,524 | 07/03/2003 | Arthur M. Krieg | Ct037,70042US00 | 4728 |
| TITLE OF INVENTION: NUCLEIC ACID COMPOSITIONS FOR STIMULATING IMMUNE RESPONSES | | | | |

| APPLN, TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1510 | \$300 | S0 | \$1810 | 04/27/2009 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHIDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DIF.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fec(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an avivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450 or Fax (571)-273-2885

for

| CURRENT CORRESPON | CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) | | | Note: A certificate of mailing can only be used for domestic mailings of Fee(s) Transmittal. This certificate cannot be used for any other accompany papers. Each additional paper, such as an assignment or formal drawing, nave its own certificate of mailing or transmission. | | | |
|--|--|--|---|---|---|---|--|
| 7590 01272909 Maria A. Trevisan Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210 | | | , | Ce | rtificate of | Mailing or Trans | |
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| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENT | OR | ATTORN | EY DOCKET NO. | CONFIRMATION NO. |
| 10/613,524 | 07/03/2003 | | Arthur M. Krieg | | C103 | 7.70042US00 | 4728 |
| APPLN, TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DU | E PREV. PAID ISSU | E FEE T | TOTAL FEE(S) DUE | DATE DUE |
| nonprovisional | NO | \$1510 | \$300 | S0 | | \$1810 | 04/27/2009 |
| EXAM | IINER | ART UNIT | CLASS-SUBCLASS | 7 | | | |
| OGUNBIYI, OI | UWATOSIN A | 1645 | 514-044000 | | | | |
| "Fee Address" ind PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A | ess an assiguee is identi h in 37 CFR 3.11. Comp | Indication formed. Use of a Customer | or agents OR, alterns (2) the name of a sir registered attorney of 2 registered patent at listed, no name will the THE PATENT (print or | ogle firm (having as a or agent) and the nam ttorneys or agents. If be printed. (type) patent. If an assign an assignment. | member a les of up to no name is | 23ified below, the do | cument has been filed : |
| | | 4l: ermitted) | D. Payment of Fee(s): (PI A check is enclosed Payment by credit c | lease first reapply ar l. ard. Form PTO-2038 by authorized to char | is attached | sly paid issue fee si | |
| 5. Change in Entity Stat a. Applicant claims NOTE: The Issue Fee and interest as shown by the re- | SMALL ENTITY status | Sec 37 CFR 1.27. | b. Applicant is no lo | onger claiming SMAL | L ENTITY | status. See 37 CF) | R 1.27(g)(2). |
| | | | | | | - | |
| Authorized Signature | N | | | Date | | | |
| Typed or printed name | | | Registration N | | | | |
| This collection of informa an application. Confidenti submitting the completed this form and/or suggestic Box 1450, Alexandria, Vi Alexandria, Viccinia, 2331 | tion is required by 37 CI ality is governed by 35 1 application form to the ons for reducing this bure raining 22313, 1150. DO | R 1.311. The informatio J.S.C. 122 and 37 CFR I USPTO. Time will vary en, should be sent to the NOT SEND FIFES OR OF | n is required to obtain or 1.14. This collection is e depending upon the ind control information Office COMPLETION ECONOMIS | r retain a benefit by the stimated to take 12 n ividual case. Any cor- cer, U.S. Patent and | ne public w ninutes to c mments on Frademark | hich is to file (and le complete, including the amount of time Office, U.S. Depart | by the USPTO to proces gathering, preparing, are you require to comple iment of Commerce, P.6 |

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCI United States Patent and Trademark United States Patent and Trademark Address: COMMISSIONER FOR PATENT P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO | |
|--|----------------|----------------------|---------------------------------|-----------------|--|
| 10/613,524 | 07/03/2003 | Arthur M. Krieg | C1037.70042US00 | 4728 | |
| 7: | 590 01/27/2009 | | EXAM | INER | |
| Maria A. Trevisan Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210 | | | OGUNBIYI, OLUWATOSIN A | | |
| | | | ART UNIT | PAPER NUMBER | |
| | | | 1645 DATE MAILED: 01/27/2009 |) | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 752 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 752 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.



NUCLEIC ACID COMPOSITIONS FOR STIMULATING IMMUNE 04-24-10/613.524 RESPONSES 2009::09:47:37 Patent Term Adjustments Patent Term Adjustment (PTA) for Application Number: 10/613,524 Filing or 371(c) Date: 07-03-2003 USPTO Delay (PTO) Delay (days): 941 Issue Date of Patent: Three Years: Pre-Issue Petitions (days): +0 Applicant Delay (APPL) Delay (days): 189 Post-Issue Petitions (days): Total PTA (days): +0 752 USPTO Adjustment(days): +0 Explanation Of Calculations Patent Term Adjustment History Date Contents Description PTO(Davs) APPL(Days) 01-27-2009 Mail Notice of Allowance 01-22-2009 Document Verification 01-21-2009 Notice of Allowance Data Verification Completed 01-21-2009 Case Docketed to Examiner in GAU 01-21-2009 Examiner's Amendment Communication 01-12-2009 Examiner Interview Summary Record (PTOL - 413) 12-22-2008 Information Disclosure Statement (IDS) Filed 12-10-2008 Reference capture on IDS 12-10-2008 Information Disclosure Statement (IDS) Filed 12-22-2008 Information Disclosure Statement considered 12-10-2008 Information Disclosure Statement considered 12-22-2008 Information Disclosure Statement (IDS) Filed 12-10-2008 Information Disclosure Statement (IDS) Filed 11-17-2008 Date Forwarded to Examiner 11-17-2008 Date Forwarded to Examiner 10-30-2008 Request for Continued Examination (RCE) 92 DISPOSAL FOR A RCE/CPA/129 (express abandonment if 11-17-2008 CPA) 10-30-2008 Request for Extension of Time - Granted 10-30-2008 Workflow - Request for RCE - Begin 04-30-2008 Mail Final Rejection (PTOL - 326) 04-28-2008 Final Rejection 02-12-2008 Date Forwarded to Examiner 01-02-2008 Response after Non-Final Action 97 01-02-2008 Request for Extension of Time - Granted 06-27-2007 Mail Non-Final Rejection 06-11-2007 Non-Final Rejection 04-29-2004 Information Disclosure Statement considered 10-27-2004 Information Disclosure Statement considered

Information Disclosure Statement considered

Information Disclosure Statement considered

03-21-2005

12-08-2006

| 05-18-2007 | Date Forwarded to Examiner | |
|------------|--|-----|
| 05-07-2007 | Response to Election / Restriction Filed | |
| 04-02-2007 | Mail Restriction Requirement | 941 |
| 03-29-2007 | Requirement for Restriction / Election | ŵ |
| 12-08-2006 | Reference capture on IDS | 1 |
| 12-08-2006 | Information Disclosure Statement (IDS) Filed | 1 |
| 12-08-2006 | Information Disclosure Statement (IDS) Filed | 1 |
| 11-01-2006 | Miscellaneous Incoming Letter | 企 |
| 07-27-2006 | Preliminary Amendment | ŵ |
| 08-01-2006 | Error(s) in CRF Corrected by STIC | 1 |
| 06-22-2006 | Mail Letter Requiring CRF (Unreadable, Non-Compliant, Not Submitted) | ŵ |
| 06-20-2006 | CRF Diskette Unreadable / Did Not Comply / Required but Not Submitted | • |
| 06-15-2006 | Case Docketed to Examiner in GAU | 金 |
| 04-05-2006 | Case Docketed to Examiner in GAU | 金 |
| 12-01-2005 | IFW TSS Processing by Tech Center Complete | 1 |
| 03-21-2005 | Information Disclosure Statement (IDS) Filed | 4 |
| 03-21-2005 | Information Disclosure Statement (IDS) Filed | 1 |
| 10-27-2004 | Reference capture on IDS | ŵ |
| 10-27-2004 | Information Disclosure Statement (IDS) Filed | 1 |
| 10-27-2004 | Information Disclosure Statement (IDS) Filed | 1 |
| 08-31-2004 | Case Docketed to Examiner in GAU | 4 |
| 04-29-2004 | Reference capture on IDS | • |
| 04-29-2004 | Information Disclosure Statement (IDS) Filed | 1 |
| 04-29-2004 | Information Disclosure Statement (IDS) Filed | • |
| 06-25-2004 | Receipt of all Acknowledgement Letters | 4 |
| 04-29-2004 | New or Additional Drawing Filed | 1 |
| 05-03-2004 | Receipt of Acknowledgment Letter | 1 |
| 01-27-2004 | Application Return from OIPE | 1 |
| 01-27-2004 | Application Return TO OIPE | * |
| 01-27-2004 | Application Dispatched from OIPE | 1 |
| 01-28-2004 | Application Is Now Complete | 1 |
| 01-12-2004 | Payment of additional filing fee/Preexam | 4 |
| 07-03-2003 | Claim Preliminary Amendment | 金 |
| 01-12-2004 | A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic | 4 |
| 11-12-2003 | Receipt of Acknowledgment Letter | 1 |
| 11-12-2003 | Notice MailedApplication IncompleteFiling Date Assigned | * |
| 10-27-2003 | Agency Referral Letter Mailed | 1 |
| 10-09-2003 | Agency Referral Letter Mailed | ŵ |
| 10-09-2003 | Agency Referral Letter Mailed | 企 |

| 10-08-2003 | Referred by L&R for Third-Level Security Review. Agency Referral Letter Generated | 1 |
|------------|--|---|
| 10-08-2003 | Referred by L&R for Third-Level Security Review. Agency Referral Letter Generated | Ŷ |
| 10-08-2003 | Referred by L&R for Third-Level Security Review. Agency Referral Letter Generated | * |
| 10-07-2003 | Referred to Level 2 (LARS) by OIPE CSR | 4 |
| 08-12-2003 | IFW Scan & PACR Auto Security Review | 企 |
| 08-06-2003 | CRF Is Good Technically / Entered into Database | ŵ |
| 07-03-2003 | CRF Disk Has Been Received by Preexam / Group / PCT | ŵ |
| 07-03-2003 | Initial Exam Team nn | ŵ |
| | | |

Close Window

| | Exhi | oit 3 |
|--|--|--|
| | Application No. | Applicant(s) |
| Examiner-Initiated Interview Summary | 10/613,524 | KRIEG, ARTHUR M. |
| , | Examiner | Art Unit |
| | OLUWATOSIN OGUNBIYI | 1645 |
| All Participants: | Status of Application: | |
| (1) <u>OLUWATOSIN OGUNBIYI</u> . | (3) | |
| (2) <u>Maria Trevisan</u> . | (4) | |
| Date of Interview: 12 January 2009 | Time: | |
| | nt's representative) | |
| Exhibit Shown or Demonstrated: Yes No If Yes, provide a brief description: | | |
| Part I. | | |
| Rejection(s) discussed: n/a | | |
| Claims discussed: n/a | | |
| Prior art documents discussed: n/a | | |
| Part II. | | |
| SUBSTANCE OF INTERVIEW DESCRIBING THE GENER Ms. Trevisan authorized proposed examiners amendment. | RAL NATURE OF WHAT WAS | DISCUSSED: |
| Part III. | | |
| It is not necessary for applicant to provide a separate re directly resulted in the allowance of the application. The of the interview in the Notice of Allowandbility. It is not necessary for applicant to provide a separate re did not result in resolution of all issues. A brief summary | examiner will provide a writte cord of the substance of the | n summary of the substance interview. since the interview. |
| and the result in resolution of all issues. A Dilet Summary | by the examiner appears in P | ait ii abuve. |
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(Applicant/Applicant's Representative Signature - if appropriate)